



10024450, 10013032

#4

DECLARATION FOR PATENT APPLICATION

As the below-named inventors, we hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled METHODS OF DETECTING AND TREATING MICROSATELLITE-INSTABILITY POSITIVE TUMORS USING RIZ, the specification of which

\_\_\_\_\_ is attached hereto as Attorney Docket No. \_\_\_\_\_.

XX was filed on December 17, 2001, as Application Serial No. 10/024,450 Attorney Docket No. P-LJ 5101)

and was amended on (or amended through) \_\_\_\_\_.  
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment(s) referred to above.

I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to myself to be material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56.

Under Sec. 1.56, information is material to patentability when it is not cumulative to information already of

Inventors: Hauang and Chadwick  
 Serial No.: 10/024,450  
 Filed: December 17, 2001  
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record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (a) Opposing an argument of unpatentability relied on by the U.S. Patent and Trademark Office, or (b) Asserting an argument of patentability.

I hereby claim the benefit under Title 35, United States Code, § 119(e) of the United States provisional application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application(s) in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose information that is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 that became available between the filing date of the prior application(s) listed below and the filing date of this non-provisional application:

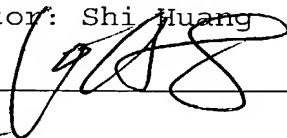
<u>Application Serial No.</u>	<u>Filing Date</u>	<u>Status</u>
60/256,582	December 19, 2000	Abandoned

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

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United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor: Shi Huang

Inventor's signature: 

Date: 5-29-02

Residence: San Diego, California USA

Citizenship: China

Mailing Address: 5296 Timber Branch Way  
San Diego, California 92103

Full name of second inventor: Robert B. Chadwick

Inventor's signature: \_\_\_\_\_

Date: \_\_\_\_\_

Residence: Castro Valley, California USA

Citizenship: United States of America

Mailing Address: 5719 Shadow Ridge Drive  
Castro Valley, California 94552



10/024,450, 10/024,450

Inventors: Hauang and Chadwick  
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United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor: Shi Huang

Inventor's signature: \_\_\_\_\_

Date: \_\_\_\_\_

Residence: San Diego, California USA

Citizenship: China

Mailing Address: 5296 Timber Branch Way  
San Diego, California 92103

Full name of second inventor: Robert B. Chadwick

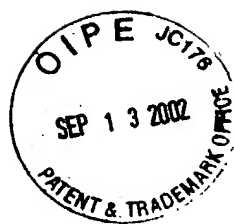
Inventor's signature: *Robert B. Chadwick*

Date: 7/24/02

Residence: Castro Valley, California USA

Citizenship: United States of America

Mailing Address: 5719 Shadow Ridge Drive  
Castro Valley, California 94552



PATENT

Our Docket: P-LJ 5101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:                    )  
     Huang and Chadwick                    )  
   )  
 Serial No.    10/024,450                    )  
   )  
 Filed: December 17, 2001                    )  
   )  
 For: METHODS OF DETECTING AND            )  
       TREATING MICROSATELLITE-            )  
       INSTABILITY POSITIVE                )  
       TUMORS USING RIZ                    )  
   )

Commissioner for Patents  
 Washington, D.C. 20231

Sir:

**SMALL ENTITY STATEMENT**

The U.S. Patent and Trademark (USPTO) permits parties that establish status as a Small Entity to pay certain reduced fees (all citations to 37 C.F.R. § 1.27 except as noted). To be entitled to Small Entity Status, a party must be at least one of the following:

**(1) Individual person:**

An individual person, including an inventor and persons to whom an inventor has transferred some rights in the invention. § 1.27(a)(1).

**(2) Small business concern:**

A business concern whose number of employees, including affiliates, does not exceed 500 persons. § 1.27(a)(2) (incorporating 13 C.F.R. § 121.802).

"Business concern" means individual proprietorship, partnership, limited liability company, corporation,

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joint venture, association, trust or cooperative. If the concern is a joint venture, participation by foreign business entities may not be more than 49%. 13 C.F.R. § 121.105.

The "number of employees" is the average number of employees, including the employees of its domestic and foreign affiliates, based on numbers of employees for each of the pay periods for the preceding completed 12 calendar months. "Employees" includes all individuals employed on a full-time, part-time, temporary, or other basis. Part-time and temporary employees are counted the same as full-time employees. If a concern has not been in business for 12 months, use the average number of employees for each of the pay periods it has been in business. 13 C.F.R. § 121.106.

Concerns are "affiliates" of each other when one concern directly or indirectly controls or has the power to control the other, or when a third party or parties controls or has the power to control both concerns. 13 C.F.R. § 121.103(a).

**(3) Nonprofit organization:**

A university or other institution of higher education located in any country. § 1.27(a)(3)(ii)(A).

An organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a). Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(B), (D).

A nonprofit scientific or educational organization qualified under a nonprofit organization statute of a U.S. state. Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(C), (D).

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Please note that a license to the Government resulting from a rights determination under Executive Order 10096 does not constitute a license that would prohibit claiming Small Entity Status. Similarly, for small business concerns and nonprofit organizations, a license to a Federal agency resulting from a funding agreement with that agency under 35 U.S.C. § 202(c)(4) is not a license that would prohibit claiming Small Entity Status. § 1.27(a)(4).

I hereby assert that I am empowered to sign on behalf of the party identified below ("Party"). Persons empowered to sign include, but are not limited to, an inventor him- or herself or an authorized officer of an assignee or licensee. See § 1.27(c)(2).

I have made a determination of the Party's entitlement to Small Entity Status, including a determination that all parties holding rights in the invention qualify for Small Entity Status. § 1.27(f).

I hereby assert that the Party has not assigned, granted, conveyed or licensed--and is under no obligation under contract or law to do so--any rights in the invention to any other party that would not qualify as a Small Entity. If the rights in the invention held by the Party are not exclusive, the other parties having rights in the invention are **The Ohio State University** and **Dcantix, Inc.** Separate assertions of Small Entity Status should be obtained from each party having rights to the invention.

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I hereby assert that the Party is entitled to be accorded Small Entity Status by the USPTO for the application or patent identified above. § 1.27(c)(1).

I understand that Small Entity Status must be newly determined when the issue fee and each maintenance fee is due. If there is any change resulting in loss of entitlement to Small Entity Status, I acknowledge the duty to file a notification to the USPTO in this application or patent before or upon paying the fee. § 1.27(g).

I understand that Small Entity Status must be separately established in any related application, including continuation, divisional, continuation-in-part, continued prosecution application or reissue application. § 1.27(c)(4).

I understand that any attempt to establish Small Entity Status improperly, deceptively or fraudulently will be considered a fraud practiced on the USPTO and may result in abandonment of the application or jeopardize the validity and enforceability of any resulting patent. § 1.27(h).

August 16, 2002  
Date

John Campbell  
Name: John Campbell  
Title: Director of Intellectual Property

THE BURNHAM INSTITUTE  
10901 North Torrey Pines Road  
La Jolla, California 92037





POWER OF ATTORNEY FOR PATENT APPLICATION BY ASSIGNEE

Assignee The Burnham Institute is a co-owner of the entire right, title and interest of U.S. patent application Ser. No. 10/024,450, filed on December 17, 2001, as attorney docket number P-LJ 5101, and entitled METHODS OF DETECTING AND TREATING MICROSATELLITE-INSTABILITY POSITIVE TUMORS USING RIZ, and any subsequently filed divisional, continuation, continuation-in-part or reissue application, including international and foreign applications claiming priority thereto.

The Assignee hereby appoints the following attorneys to prosecute these applications and to transact all related business in the United States Patent and Trademark Office and any international and foreign patent offices:


CATHRYN CAMPBELL, Registration No. 31,815; DAVID A. GAY, Registration No. 39,200; CALVIN A. FAN, Registration No. 38,444; ANDREA L. GASHLER, Registration No. 41,029; JAMES J. WONG, Registration No. 34,949; DEBORAH L. CADENA, Registration No. 44,048; MELANIE K. WEBSTER, Registration No. 45,201; ASTRID R. SPAIN, Registration No. 47,956; and KIMBERLY J. PRIOR, Registration No. 41,483.

Please direct all telephone calls to Cathryn Campbell at (858) 535-9001 and address all correspondence to:

CATHRYN CAMPBELL  
CAMPBELL & FLORES LLP  
4370 La Jolla Village Drive  
7<sup>th</sup> Floor  
San Diego, California 92122  
USPTO CUSTOMER NO. 23601

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The undersigned is authorized to sign on behalf of the  
Assignee.

Signature:   
Name (typed): John Campbell  
Title: Director of Intellectual Property  
Assignee: THE BURNHAM INSTITUTE  
Date: May 21, 2002



ONE EXECUTED STATEMENT UNDER 37  
C.F.R. § 3.73 (b) WITH ATTACHED  
COPIES OF TWO ASSIGNMENTS (7 pages)  
Attorney Docket No: P-LJ 5101

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

"EXPRESS MAIL" MAILING LABEL NUMBER: EV 065 744 855 US

DATE OF DEPOSIT: September 13, 2002

I HEREBY CERTIFY THAT THIS PAPER OR FEE IS BEING DEPOSITED WITH THE  
UNITED STATES POSTAL SERVICE "EXPRESS MAIL POST OFFICE TO  
ADDRESSEE" SERVICE UNDER 37 CFR 1.10 ON THE DATE INDICATED ABOVE  
AND IS ADDRESSED TO COMMISSIONER FOR PATENTS, WASHINGTON, D.C.  
20231.

Rebecca McElroy

Printed Name of Person Mailing Paper or Fee

Rebecca McElroy

Signature of Person Mailing Paper or Fee

STATEMENT UNDER 37 C.F.R. § 3.73(b)

Title of Application: METHODS OF DETECTING AND TREATING  
MICROSATELLITE-INSTABILITY POSITIVE  
TUMORS USING RIZ

Application Ser. No.: 10/024,450

Filed: December 17, 2001

Inventor(s): Huang and Chadwick

Attorney Docket No.: P-LJ 5101

THE BURNHAM INSTITUTE, a non-profit organization, states that it is a co-assignee with The Ohio State University of the entire right, title and interest in the patent application identified above by virtue of an assignment from an inventor of the application. A copy of the executed assignment, submitted for recording, is attached hereto as documentary evidence of the chain of title to the assignee.

The undersigned is empowered to sign this statement on behalf of the assignee.

Date: May 21, 2002

Signature: \_\_\_\_\_

Name: John Campbell

Title: Director of Intellectual Property

COPY

ASSIGNMENT

This Assignment is made by Shi Huang of San Diego, California, Assignor, to The Burnham Institute, Assignee, having a place of business at 10901 North Torrey Pines Road, La Jolla, California 92037.

WHEREAS, Assignor is a joint inventor of a new and useful METHODS OF DETECTING AND TREATING MICROSATELLITE-INSTABILITY POSITIVE TUMORS USING RIZ for which an application for United States Letters Patent was filed on December 17, 2001, in the United States Patent and Trademark Office, bearing Serial No. 10/024,450, and identified as Attorney Docket No. P-LJ 5101.

WHEREAS, Assignor believes that Assignor is one of the original joint inventors of the invention disclosed and claimed in said application for Letters Patent; and

WHEREAS, the parties desire to have a recordable instrument assigning the entirety of Assignor's right, title and interest in and to said invention, said application and any Letters Patent that may be granted for said invention in the United States and throughout the world;

NOW, THEREFORE, in accordance with the obligations to assign the invention and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Assignor sells, assigns, and transfers to Assignee, the entirety of Assignor's right, title, and interest in and to said invention, said application, any applications entitled to benefit of priority to said application under Title 35, United States Code, Sections 120, 121 or 251, which include divisionals, continuations and reissues, and any Letters Patent that may be granted on said invention or these applications and any Letters Patent that may be granted for said invention in the United States and throughout the world, including the right to file foreign applications directly in the name of the Assignee and to claim for any such foreign applications any priority rights to which such applications are entitled under international conventions, treaties, or otherwise.

Assignor agrees that, upon request and without further compensation, but at no expense to Assignor, Assignor and Assignor's legal representatives and assigns will do all lawful acts, including the execution of papers and the giving of testimony, that may be necessary or desirable for obtaining, sustaining, reissuing, or enforcing Letters Patent in the United States and throughout the world for said invention, and for

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perfecting, recording, or maintaining the title of Assignee, its successors and assigns, to said invention, said application, and any Letters Patent granted for said invention in the United States and throughout the world.

Assignor represents and warrants that Assignor has not granted and will not grant to others any rights inconsistent with the rights granted herein.

Assignor authorizes and requests the Commissioner of Patents and Trademarks and all foreign countries to issue any Letters Patent granted for said invention, whether on said application or on any subsequently filed divisional, continuation, or reissue application, to Assignee, its successors and assigns, as an assignee of the entirety of Assignor's interest in said invention.

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IN WITNESS WHEREOF, Assignor has executed this  
 Assignment on the date(s) provided below.

Assignor: Shi Huang

[Signature]  
 Signature

5-29-02

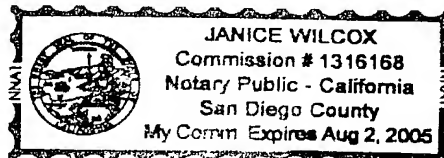
Date

STATE OF California )  
 COUNTY OF San Diego )

On May 29<sup>th</sup> 2002, before me, Janice Wilcox  
 personally appeared Shi Huang,  
~~X~~ personally known to me - OR - proved to me on the basis  
 of satisfactory evidence to be the person(s) whose name(s) is/are  
 subscribed to the within instrument and acknowledged to me that  
 he/she/they executed the same in his/her/their authorized  
 capacity(ies), and that by his/her/their signature(s) on the  
 instrument the person(s), or the entity upon behalf of which the  
 person(s) acted, executed the instrument.

WITNESS by hand and official seal.

[Signature]  
 (Signature of Notary)



COPY

ASSIGNMENT

This Assignment is made by Robert Chadwick of Bothell, Washington, Assignor, to The Ohio State University, Assignee, having a place of business at 1960 Kenny Road, Columbus, Ohio, 43210.

WHEREAS, Assignor is a joint inventor of a new and useful METHODS OF DETECTING AND TREATING MICROSATELLITE-INSTABILITY POSITIVE TUMORS USING RIZ for which an application for United States Letters Patent was filed on December 17, 2001, in the United States Patent and Trademark Office, bearing Serial No. 10/024,450, and identified as Attorney Docket No. P-LJ 5101.

WHEREAS, Assignor believes that Assignor is one of the original joint inventors of the invention disclosed and claimed in said application for Letters Patent; and

WHEREAS, the parties desire to have a recordable instrument assigning the entirety of Assignor's right, title and interest in and to said invention, said application and any Letters Patent that may be granted for said invention in the United States and throughout the world;

NOW, THEREFORE, in accordance with the obligations to assign the invention and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Assignor sells, assigns, and transfers to Assignee, the entirety of Assignor's right, title, and interest in and to said invention, said application, any applications entitled to benefit of priority to said application under Title 35, United States Code, Sections 120, 121 or 251, which include divisionals, continuations and reissues, and any Letters Patent that may be granted on said invention or these applications and any Letters Patent that may be granted for said invention in the United States and throughout the world, including the right to file foreign applications directly in the name of the Assignee and to claim for any such foreign applications any priority rights to which such applications are entitled under international conventions, treaties, or otherwise.

Assignor agrees that, upon request and without further compensation, but at no expense to Assignor, Assignor and Assignor's legal representatives and assigns will do all lawful acts, including the execution of papers and the giving of testimony, that may be necessary or desirable for obtaining, sustaining, reissuing, or enforcing Letters Patent in the United States and throughout the world for said invention, and for



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Filed: December 17, 2001  
Attny Docket: P-LJ 5101  
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perfecting, recording, or maintaining the title of Assignee, its successors and assigns, to said invention, said application, and any Letters Patent granted for said invention in the United States and throughout the world.

Assignor represents and warrants that Assignor has not granted and will not grant to others any rights inconsistent with the rights granted herein.

Assignor authorizes and requests the Commissioner of Patents and Trademarks and all foreign countries to issue any Letters Patent granted for said invention, whether on said application or on any subsequently filed divisional, continuation, or reissue application, to Assignee, its successors and assigns, as an assignee of the entirety of Assignor's interest in said invention.

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 Filed: December 17, 2001  
 Attny Docket: P-LJ 5101  
 Page 3

IN WITNESS WHEREOF, Assignor has executed this  
 Assignment on the date(s) provided below.

Assignor: Robert B. Chadwick

[Signature] 7/24/02  
 Signature Date

STATE OF California )  
 COUNTY OF Alameda )

On July 25, 2002 before me Cora Judd  
 personally appeared Robert B. Chadwick,  
 personally known to me - OR - ☒ proved to me on the basis  
 of satisfactory evidence to be the person(s) whose name(s) is/are  
 subscribed to the within instrument and acknowledged to me that  
he/she/they executed the same, in his/her/their authorized  
 capacity(ies), and that by his/her/their signature(s) on the  
 instrument the person(s), or the entity upon behalf of which the  
 person(s) acted, executed the instrument.

WITNESS by hand and official seal.

[Signature]  
 (Signature of Notary)

